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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,408	12/11/2000	Ronald K. Yamamoto	ISC9901U	4638

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LEARY & ASSOCIATES
3900 NEWPARK MALL RD.
THIRD FLOOR, SUITE 317
NEWARK, CA 94560

EXAMINER

VIRDI, SUNDEEP

ART UNIT PAPER NUMBER

3763

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/735,408

Applicant(s)

YAMAMOTO ET AL.

Examiner

Sundeep S Virdi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8, 10, 18-29, 31-34, 37-39, 42, 45 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 10, 18-29, 31-34, 37-39, 42, 45 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 15 October 2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 20, 24 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Shahidi (6,167,296).

Shahidi discloses an apparatus comprising a locating means (column 3, lines 22-27; figure 5, 105-108) that could be used non-invasively to locate Schlemm's Canal in an eye that is coupled with a microsurgical device (figures 1 and 2, 109) that could be advanced into a tissue space identified with Schlemm's Canal, where the surgical device is under control by the locating means (a computer program is integrated with

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the location means and the program provides instruction as to where the surgical instrument is located at a given point during a surgical procedure thereby guiding a surgeon where he should be using the surgical instrument and therefore the location means controls where a surgeon should be using the surgical instrument during a procedure; see figures 1-8), and where the locating means comprises a device that could be used for ultrasound examination of the sclera (column 7, lines 37-41) or an ultrasound imaging system (figure 4).

With regards to claim 20, broadly interpreted, the endoscope (109, column 4, line 8) disclosed in Shahidi is a microcannula.

With regards to claim 24, the locating means (110, 111) and the microcannula (109) are disposed within a unitary body (see figure 1).

With regards to claim 32, the microcannula (109) is coupled coaxially with the locating means (ultrasound transducer 115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Jones (3,941,122).

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Shahidi discloses the claimed invention as discussed earlier. However, Shahidi does not disclose using an ultrasound device with an ultrasound frequency greater than 10 MHz or an ultrasound frequency of at least 40 MHz.

Jones teaches the use of an ultrasound frequency of 90 MHz-100 MHz in ophthalmic applications in order to dissolve unwanted material in the eye in a very localized region without deleteriously affecting the surrounding tissue (column 6, lines 28-31). Frequencies of 90-100 MHz are greater than 10 MHz and are at least 40 MHz.

It would have been obvious to one of ordinary skill in the art to modify the ultrasound device in Shahidi to enable it to operate at 90-100 MHz in order to dissolve unwanted material in the eye in a very localized region without deleteriously affecting the surrounding tissue as taught by Jones.

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Bernstein (6,132,699).

Shahidi discloses the claimed invention as discussed earlier. However, Shahidi does not disclose utilizing an ultrasound contrast tracer.

Bernstein teaches the use of an ultrasound contrast introduced into the body in order to enhance detection and observation of certain physiological and pathological conditions (column 1, lines 29-33).

It would have been obvious to one of ordinary skill in the art to modify the claimed invention as disclosed in Shahidi and modify it by utilizing an ultrasound contrast agent as taught by Bernstein in order to enhance detection and observation of certain physiological and pathological conditions.

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5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of LeBlanc et al (5,989,189).

Shahidi discloses the claimed invention as discussed earlier. However, Shahidi does not disclose the locating means comprising a transducer assembly with signaling means for directing the transducer location.

LeBlanc et al teaches the use of an ultrasound transducer with a signaling means in order to detect, not only typical eye structures such as the cornea, retina, sclera, etc., but also aberrations such as tumors and blood trapped within an eye's vitreous (column 1, lines 16-27).

It would have been obvious to one of ordinary skill in the art to modify the claimed invention as disclosed in Shahidi and modify it by incorporating a transducer assembly with a signaling means in order to detect, not only typical eye structures such as the cornea, retina, sclera, etc., but also aberrations such as tumors and blood trapped within an eye's vitreous.

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Schachar (6,146,366).

Shahidi discloses the claimed invention as discussed earlier. However, Shahidi does not disclose a tissue-contacting surface of the locating means being curved to approximate the surface of the eye.

Schachar teaches the use of a device used for the treatment of eye disorders, which has a surface that contacts the eye, which is curved in order to provide an

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approximate match for the curvature of the surface of the eye (figure 6, column 9, lines 53-56).

It would have been obvious to one of ordinary in the art to modify the claimed invention as disclosed in Shahidi and modify it by incorporating a tissue contacting surface of the locating means which is curved in order to provide an approximate match for the curvature of the surface of the eye as taught by Schachar.

7. Claims 19, 27, 28, 29, 31 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Steen et al (5,984,904).

Shahidi discloses the claimed invention as discussed earlier. However, with regards to claim 19, Shahidi does not disclose a tissue-contacting surface of the locating means incorporating a circumferential raised portion to maintain placement of a coupling fluid over a transducer face.

Steen teaches the use of a surgical instrument used to perform eye surgery which contains several raised portions in the form of an array of protuberances projecting from an interior wall surface and spaced apart in longitudinal and transverse directions so as to define a network of generally uniform channels extending between adjacent protuberances for fluid flow about each protuberance in longitudinal and transverse directions (figures 4-7, 40; column 4, lines 7-12). These protuberances extend are formed along the interior wall and are shown as covering one interior circular wall in order form channels to maintain placement of a fluid (figure 4, 40)

It would have been obvious to one of ordinary skill in the art to modify the invention of Shahidi with the protuberances as taught by Steen in order to form a

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channel to maintain placement of a fluid and to extend the concept of raised protuberances to extend around the entire circumference of an instrument (column 3, lines 3-6).

With regards to claim 27 and 29, Shahidi does not disclose a microcannula or inner cannula incorporating a cutting tip to penetrate a sclera of an eye.

Steen teaches the use of a microcannula (inner cannula)(26) with a cutting tip (16) used to remove the natural lens from an eye during a surgical procedure conducted on the eye.

It would have been obvious to one of ordinary skill in the art to modify the microcannula (109, column 4, line 8) of Shahidi and incorporate a cutting tip as taught by Steen in order to remove the natural lens from an eye during a surgical procedure.

With regards to claim 28 and 31, Shahidi fails to disclose a microcannula that is comprised of a flexible outer sheath and an inner cannula.

Steed teaches the use of a pliable outer sheath (10) (column 2, lines 55-58) and an inner cannula (26) in order for insertion in the eye during surgery.

It would have been obvious to one of ordinary skill in the art to modify the microcannula of Shahidi (109) and use as the surgical instrument a microcannula composed of a flexible outer sheath and an inner cannula as taught by Steed in order for insertion in the eye during surgery.

With regards to claim 46, Shahidi discloses the claimed invention. However, Shahidi does not disclose the use of a construct delivered through a microcannula which comprises a surgical tool for cutting tissues.

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Steed teaches the use of a construct (16) delivered through a microcannula (26) which comprises a surgical tool for cutting tissues, in order to remove the natural lens from an eye during a surgical procedure.

It would have been obvious to one of ordinary skill in the art to modify the invention of Shahidi and incorporate a surgical tool for cutting tissues delivered through a microcannula in order to remove the natural lens from an eye during a surgical procedure.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi. Shahidi discloses a microcannula (109, column 4, line 8) but does not specify a size of less than 200 microns. It would have been obvious to one of ordinary skill in the art to modify the microcannula of Shahidi and limit its size to being less than a specific measurement, such as 200 microns in order to accommodate using the cannula in a correspondingly small space that would require the cannula to be less than 200 microns.

9. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Imling et al (6,203,499).

Shahidi discloses the claimed invention as discussed earlier. However, Shahidi does not disclose the microcannula of Shahidi being coupled to the locating means at an adjustable angle such as between 0 and 30 degrees.

Imling teaches the use of a multiple angle needle guide that can be coupled to an imaging system (column 1, lines 36-44) in order to allow the needle to be adjusted to any angle, such as between 0 and 30 degrees (figure 1).

It would have been obvious to one of ordinary skill in the art to modify the cannula of Shahidi and utilize a multiple angle needle guide as taught by Imling so that a needle can be coupled to the locating means at an angle between 0 and 30 degrees or any other angle in order to ensure that the needle can be effectively maneuvered in the direction indicated by the locating means.

10. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Simon (4,883,053).

Shahidi discloses the claimed invention as discussed earlier. However, Shahidi does not disclose the microcannula being coupled to the locating means using a clip mechanism.

Simon teaches the use of a clip mechanism (68a, 68b) in order to couple a cannula (66) to another device (50) in order to securely couple the cannula to the device.

It would have been obvious to one of ordinary skill in the art to modify the invention of Shahidi and incorporate a clip mechanism as taught by Simon in order to securely couple the cannula to the locating means.

11. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Mohr, Jr. et al (5,921,954).

Shahidi discloses the claimed invention as discussed earlier. However, Shahidi does not disclose a distal portion of the microcannula being curved to accommodate a curvature of Schlemm's Canal.

Mohr, Jr. discloses a cannula to be used in treating a myriad of body structures, where the cannula tip (101) may comprise a curved needle-like shape adapted to a surface curvature of an eye, so the cannula tip 101 may be inserted into an eyelid (column 3, lines 39-42).

It would have been obvious to one of ordinary skill in the art to modify the cannula of Shahidi by curving the tip of the cannula such that it would be adapted to the surface curvature of an eye so that it may be inserted into an eyelid as taught by Mohr, Jr.

12. Claims 32-34, 38 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Lynch et al (6,524,275).

Shahidi discloses the claimed invention as discussed earlier. However, Shahidi does not disclose a dilation mechanism on the tip of the cannula.

Lynch discloses an inflatable device and method for treating glaucoma that teaches the use of a dilation mechanism on the tip of a cannula (50), which consists of an inflatable sleeve (and broadly speaking, a balloon is an inflatable sleeve) which is placed within Schlemm's canal and the inflatable element of the device is expanded to temporarily stretch and expand the lumen of the canal. At that point, the inflatable element may be used to temporarily occlude outflow through the canal, while physiologic material is injected through another lumen of the device, thereby distending the canal and expanding areas of stenosis within the canal (column 3, lines 56-65).

It would have been obvious to one of ordinary skill in the art to modify the cannula of Shahidi and incorporate a dilation mechanism, such as the inflatable sleeve

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(balloon) on the tip of the cannula as taught by Lynch for placement within Schlemm's canal in order to temporarily stretch and expand the lumen of the canal.

With regards to claim 38, Shahidi does not disclose an implant being delivered into Schlemm's Canal.

Lynch teaches an implant being delivered into Schlemm's Canal (column 5, lines 4-12) in order to maintain patency within the canal to facilitate the natural drainage of the aqueous humor.

It would have been obvious to one of ordinary skill in the art to modify the invention of Shahidi to include delivering an implant into Schlemm's Canal in order to maintain patency within the canal the facilitate the natural drainage of the aqueous humor.

With regards to claim 45, Shahidi does not disclose a construct being delivered through a microcannula.

Lynch teaches a construct being delivered (column 5, lines 4-12) through a microcannula (100) to effect a surgical procedure on a trabecular meshwork of the eye (column 7, lines 15-19).

It would have been obvious to one of ordinary skill in the art to modify the invention of Shahidi to include delivering a construct through a microcannula in order to effect a surgical procedure on a trabecular meshwork of the eye.

13. Claims 39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahidi in view of Lafont et al (5,957,975).

Shahidi discloses the claimed invention as discussed earlier. However, Shahidi does not disclose the use of an expandable or biodegradable stent.

Lafont teaches the use of an expandable biodegradable stent for the purpose of enlarging a lumen or canal within the body that will degrade within the body and eliminates the need for removal of the stent.

It would have been obvious to one of ordinary skill in the art to modify the invention of Shahidi and add an expandable stent for the purpose of enlarging a lumen or canal within the body, such as Schlemm's Canal that will degrade with the body and eliminate the need for removal of the stent.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dunne (6,198,956) discloses an ultrasonic scanning device. Buscemi (5,593,403) discloses a biodegradable stent. Smith et al (5,515,853) discloses a three-dimensional digital ultrasound tracking system. Stegmann (5,360,399) discloses a method and apparatus for maintaining the normal intraocular pressure. Ritch et al (5,092,837) discloses a method for the treatment of glaucoma. Scribner et al (5,054,492) discloses an ultrasonic imaging catheter. Coleman et al (4,932,414) discloses a system of therapeutic ultrasound and real-time ultrasonic scanning. Tam (4,866,614) discloses an ultrasound characterization of three dimensional flaws. Taenzer (4,237,901) discloses an low and constant pressure transducer probe for an ultrasonic diagnostic system. Green et al (4,141,347) discloses an ultrasonic imaging


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method. Eggleton et al (3,735,755) discloses a non-invasive surgery method and apparatus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sundeep S Virdi whose telephone number is 703-305-0499. The examiner can normally be reached on M-F 9am-5:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700


Sundeep Virdi
Art Unit 3763